K003347

FEB 2 3 2001

510(k) Summary

Submitter: Kinamed, Inc.

Address: 2192 C Anchor Court
Newbury Park, CA 91320

Phone number: (805) 499-5999

Fax number: (805) 499-8684

Contact person: William Pratt

Date prepared: October 20, 2000

Trade name: OrthoPilot®

Substantial equivalence claimed to:

1. StealthStation® System with FluoroNav™ module - 510(k) Number - K990214
2. VectorVision^2 (BrainLAB Navigation System) - 510(k) Number - K983831

Description:

Orthopilot® uses three infrared transmitters that are securely mounted to the patient's bones, and a camera to monitor the spatial location of those transmitters in relation to each other and the medical instruments. These locations are used to locate the centers of rotation of the femur head, ankle, and knee. These measurements allow for greater accuracy than mechanical methods of ascertaining implantation sites and positions.

Intended use:

Orthopilot® is a system for computer-aided navigation of surgical instruments whose purpose is to optimally position the Gem™ knee endoprosthesis (K994214) in the patient. It aids the surgeon in accurately positioning the cutting guides for total knee replacement surgery and provides intraoperative measurements of bone alignment.

Summary of technological characteristics:

Orthopilot® optimally positions the Gem™ knee endoprosthesis in the patient. The patient data needed to carry out this procedure is recorded intraoperatively. Preoperative CT-scanning is unnecessary. The link between patient and computer is established by three infrared transmitters that are attached to the patient. An infrared camera that is linked to the computer localises these infrared transmitters.

The instruments are also outfitted with infrared transmitters and can therefore be brought into a spatial relationship with the patient, with the aid of the computer. The system uses infra-red localizers and LEDs to accurately obtain the correct rotational center of the femur head, ankle, and knee. The OrthoPilot® system needs only the information provided by the LEDs to determine the correct position of the cutting guides. Intraoperative x-rays are not needed to guide the surgical procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Kinamed, Inc.
c/o Mr. Robert Joel Slomoff
9229 Cranford Drive
Potomac, Maryland 20854

Re: K003347
Trade Name: Orthopilot®
Regulatory Class: II
Product Code: HAW
Dated: January 12, 2001
Received: January 16, 2001

Dear Mr. Slomoff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003347

Device Name: Orthopilot®

Indications for Use:

Orthopilot® is a system for computer-aided navigation of surgical instruments whose purpose is to optimally position the Gem™ knee endoprosthesis (K994214) in the patient. It aids the surgeon in accurately positioning the cutting guides for total knee replacement surgery and provides intraoperative measurements of bone alignment.

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003347

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)